

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Li Wang	Examiner:	Alyssa M. Alter
Serial No.:	10/684,759	Group Art Unit:	3762
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Title:	METHOD AND APPARATUS FOR MONITORING TISSUE FLUID CONTENT FOR USE IN AN IMPLANTABLE CARDIAC DEVICE		

Reply Brief

Box Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The following Brief is submitted responsive to the Examiner's Answer of June 14, 2011.

Any required fee will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.16, 1.17, 1.136(a), or any additional fees to Deposit Account 13-2546.

Argument

The Examiner's Response to Arguments is filled with general principles of the law, accurately quoting the cited opinions. The problem is that it doesn't actually address the claim language or the arguments actually made by Applicants.

There are two new general arguments in the Examiner's Answer. Both are respectfully asserted to be inadequate in the context of an obviousness rejection.

1. Examiner's first new argument – Applicant's arguments are inapplicable to the rejection

The examiner repeatedly argues that the two references can be combined. Of course they can. Any two references can be combined consistent with their teachings. Applicants never disputed this fact. The question is whether they can be properly combined to make the invention as claimed.

In the Examiner's Answer, the examiner has advanced a new way of combining the references, different from that previously advanced, and argues that Applicant's arguments were not properly directed to this new grounds of rejection. Of course not. How could they possibly be directed to an Examiner's argument that had not yet been made?

In the Response to Argument, The Examiner emphasizes that the impedance measurement system (mechanisms) of Scheulke is now not intended to be incorporated into Combs in order to make the claimed invention. Only the general idea of using impedance to measure lead integrity is to be taken from Scheulke. With all due respect, this new argument is inconsistent with the Examiner's previous arguments which expressly require incorporation of the impedance measurement system (mechanisms) of Scheulke into Combs.

The Examiner criticizes Applicant for arguments directed to the importation of the impedance measurement system of Scheulke into the Combs device. However, the actual source for Applicant's belief that this was the issue on appeal was the Examiner herself, however much she may now wish to distance herself from her previous argument.

The Examiner previously stated as follows:

Combs et al. discloses the claimed invention except for assessing the integrity of the leads. Schuelke et al. discloses a lead integrity measuring system that measured impedance values to determine lead integrity failures. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system of Combs et al. to include a lead integrity measuring system as taught by Schuelke et al. in order to provide the predictable results of ensuring the leads are in proper working order. Furthermore, checking the integrity of the leads would ensuring the sensed values are accurate.

Applicants were merely responding to the Examiner's previous express arguments, as is entirely appropriate and correct.

If there is any doubt about this, it is respectfully noted that the Examiner herself specifically relies on the details of the impedance measuring system (the specific mechanisms, not just the general idea) in Scheulke to meet specific additional limitations of the claims. In particular, the examiner expressly argues that system of Scheulke as imported provides the impedance cross-checking mechanism of claims 86 – 87 and 102 – 103, which is acknowledged to be absent from Combs.

The Examiner previously stated:

As to claims 86-87 and 102-103, Schuelke et al. discloses a device with three leads where each lead has an electrode. Wherein the third electrode provides a cross check of measured impedance values. "Testing current and voltage lead integrity of at least one of the leads comprising the steps of and means for: selecting one of the at least three leads as a lead under test, a force lead and a measure lead; coupling the terminal of the lead under test to a fixed potential; driving an excitation voltage pulse in an excitation path including the terminal of the selected force lead, the force lead electrode/tissue interface, the lead under test electrode/tissue interface and the lead under test; measuring the excitation current value of the excitation voltage pulse delivered in the excitation path through the lead under test; and measuring an induced voltage in a measure path including the terminal of the selected measure lead, the measure lead electrode/tissue interface, the lead under test electrode/tissue interface and the lead under test". The lead impedance of the lead under test is derived from the measured excitation current value and the induced voltage value. In order to test the lead integrity of the remaining leads, the selection of the lead under test, the force lead and the measure lead are changed, and the test is repeated"(col. 4, lines 46-65). Therefore, the modified Combs et al. discloses performing a cross-check of measured impedance values with a third electrode.

In order to reject claims 86 – 87 and 102 – 103, the Examiner needed to import the entire impedance measurement system (mechanisms) of Scheulke into Combs, not just the general idea of using the Combs measurements to check lead integrity. Now

the Examiner takes the exactly the opposite position and states:

Therefore, it would have been obvious to take the already sensed impedance data from Combs et al. and further determine lead integrity as disclosed by Schuelke et al. The combination does not require additional mechanisms, and merely teaches the addition application for the already sensed impedance data.

The Examiner now thus expressly takes the position that her own previous argument for obviousness is incorrect, or at least irrelevant. What is left? In any case, the net result is an inconsistent set of statements that cannot possibly meet the requirements of clarity and common sense required for a proper Section 103 rejection.

As previously argued, Applicants argued that the combined teaching of the references teaches away from combining them in the way the Examiner previously proposed in order to meet the claims. None of Applicants' specific factual arguments were refuted in the Examiner's Response to Argument. The Examiner instead withdraws her own previous proposal for combining the references and argues that Applicant's arguments were therefore irrelevant.

Can this possibly be a sound method of rejecting claims? Applicant sincerely hopes that it is not.

It is respectfully asserted that to the extent the previous arguments are still on the table or are included somehow in the new argument, Applicant's previous arguments with regard to the combination of Combs and Scheulke still apply.

In any case, as discussed below, it is respectfully asserted that the references still do not render the claimed invention obvious, even using the Examiner's new argument. It is further noted that the New argument itself, to the extent it is explained in the Examiner's Answer, is internally inconsistent and therefore improper.

2. Examiner's second new Argument – Combs discloses everything in the claims except the general idea using the results of the impedance measurement to measure lead impedance

Under the new argument, the Examiner now takes the position that the impedance measurement system of Scheulke is not to be imported into Combs and that the impedance measuring system of Combs is to be retained intact. The only proposed change to Combs is to use the results from the Combs impedance measuring system as disclosed in order to assess lead integrity. This argument appears to be directed at all claims currently appealed.

In particular, the Examiner now states:

Therefore, it would have been obvious to take the already sensed impedance data from Combs et al. and further determine lead integrity as disclosed by Schuelke et al. The combination does not require additional mechanisms, and merely teaches the addition application for the already sensed impedance data.

There are several clear problems with this new argument. Some relate to the fact that the new proposed combination if made still doesn't meet the all of the limitations of the appealed claims. Regardless of the obviousness of making the Examiner's new proposed combination of references, it therefore cannot make these appealed claims obvious.

Others relate to the failure of the new arguments presented to clearly explain why the invention would be obvious as required by the Patent Office guidelines for obviousness rejections. In the absence of such explanations, the questions of whether the proposed modifications to the cited references meet the standard of common sense simply cannot be addressed.

Still others relate to the fact that where explanations are given, they are contradictory to the basic premise of the new argument, i.e. that mechanisms from Scheulke do not need to be imported.

The problems are discussed below as they relate to specific groups of claims.

A. Claims – 80 – 82 and 96 – 98 use of same measurement mechanism (same pulse) for respiration rate (fluid content) and lead integrity.

Claims 80 – 82 and 96 – 98 require that the same measurement pulses produce both the fluid measurement and the lead integrity measurement, and that these measurement pulses must be delivered at predetermined intervals following cardiac events. Previously, the Examiner argued that the specific mechanism of impedance measurement in Scheulke somehow made it obvious to use the same measurement pulse for both types of impedance measurement. In particular, the Examiner stated:

However, Schuelke et al. discloses “the lead integrity check may also be undertaken during delivery of a pacing pulse” (col 3, lines 22-23). Therefore, the system does not require the separate measurements, but can be used at the same time. In

As noted above, the Examiner has expressly withdrawn all arguments based upon importing the mechanisms of Scheulke into Combs. The Examiner simply states that it would be obvious to use the measurement system of Combs to measure lead integrity, without more. Given that as disclosed, Scheulke uses a substantially different system from Combs to measure lead integrity, a valid rejection should require more. For example, the requirement to set forth obviousness rejections with sufficient clarity to determine whether they conform to common sense should require some explanation of why the proposed change is obvious.

The references disclose substantially different impedance measurement mechanisms for assessing lead integrity and for measuring fluid content. This is presumably why the Examiner found it necessary to import the entire impedance measurement system from Scheulke into Combs in conjunction with the previous arguments for obviousness.

Absent more, the two references would teach away from using either mechanism to measure the other parameter. Some explanation of why doing so nonetheless conforms to common sense is clearly required under the recently issued Patent Office guidelines for obviousness rejections. The fact that both systems include measurements of impedance, in and of itself cannot be enough. All possible mechanisms of measuring impedance cannot possibly be flatly obvious to substitute for one another to measure all possible parameters. The question of obviousness is not resolved by the commonality of the word “impedance”.

The previous argument presented by the Examiner included an explanation of why that made no sense and has been withdrawn. The new rejection doesn’t even address the question of why.

The examiner’s current grounds for rejection of these claims is respectfully asserted to be per-se inadequate under the Patent Office’s own requirements.

Withdrawal of the rejections of these claims is respectfully requested.

B. Claims 86 – 87 and 102 – 103 - Cross-checking

Claims 86 – 87 and 102 – 103 are directed to inclusion of a cross-checking mechanism.

As discussed above, the Examiner previously expressly acknowledged that the Combs system does not provide cross checking and that importation of the specific

impedance measurement mechanism of Scheulke was necessary to provide these capabilities. That argument has been expressly withdrawn as under the new argument for rejection, no mechanisms are to be imported from Scheulke.

The new argument expressly excludes incorporating mechanisms from Scheulke and provides no alternative rationale for doing so. If the new argument is intended to be the basis for rejection, these claims therefore are respectfully asserted to be allowable as a matter of law over the Examiner's new argument, regardless of the patentability of the remaining claims.

Confusingly, and directly contradictory to the Examiner's new argument, the Examiner also repeats her previous inconsistent argument that the specific impedance measurement mechanisms of Scheulke provide the required cross-checking capabilities. The factual errors underlying this argument were specifically addressed in the Appeal Brief, and were apparently the issues the Examiner wished to avoid dealing with by advancing the new argument.

In any case, the present directly inconsistent arguments included in the grounds for rejection together are so unclear as to be inadequate under the Patent Office guidelines for obviousness rejections.

Withdrawal of the rejections of these claims is respectfully requested.

C. Claims 81 and 97 – Lead fault determinations rendering fluid measurements invalid.

Claims 81 and 97 require that the fluid content measurements are declared invalid responsive to detected lead faults. This feature is not disclosed in Combs, and using the existing impedance measuring system in Combs to detect lead faults does not in and of itself result in this function necessarily being performed.

The Examiner's argument is expressly based upon assertion that it this additional function would necessarily be present in Combs as modified according to the Examiner's new argument. In conjunction with this argument, in the Examiner's Answer, the Examiner states:

of record and stated above, "Furthermore, checking the integrity of the leads would ensuring the sensed values are accurate." When the integrity of the lead is compromised, the values sensed are necessarily considered to have been compromised as well. Therefore, determining the integrity would necessarily determine if the impedance data is considered flawed as well. Therefore, the modified Combs et al. does disclose the determination of the measured impedances to be flawed in response to the assessment of the lead integrity.

This argument is factually incorrect in both respects.

First, verifying lead integrity only assures that the leads themselves are intact. It does not mean all impedance measurements made using the leads are necessarily correct. Additionally, this isn't the limitation that is in the claims, and is thus irrelevant anyway. The claims deal with declaring the impedance measurements invalid, not declaring them valid.

Second, a detected lead fault does not "necessarily determine if the impedance data is considered flawed as well". The impedance data in Combs are filtered to produce a fluid measurement. For example, a gradual over-all constant increase or decrease in lead impedance does not necessarily render the measurements (fluid content measurements) based upon the difference between short and long term averages of the filtered impedance measurements inaccurate. Depending on the rate of change of lead impedance , it may well have no effect whatsoever on the determination of changes in fluid content. Clearly, if respiration cycle length is being

used as the metric if fluid content, a net increase or decrease in impedance would have no particular effect, as a baseline offset would not effect cycle length measurements. Further, the effect of intermittent faults in the leads (occasional out of bounds impedance measurements) would substantially reduced by the filtration function in the un-modified structure of Combs, so they would not “necessarily” render the impedance measurements related to fluid level invalid either.

The Examniner’s arguments that Combs as modified using the Examiner’s new argument necessarily includes this added function (declaring the fluid measurements invalid) is based upon factual mis-statements and must be found inadequate to meet the standard of common sense. A detection of a lead fault, without more, is not a declaration that the fluid measurement is invalid

Withdrawal of the rejections of claims 81 and 97 is respectfully requested.

D. Claims 84, 85, 99, 100 and 101 - Declaring fluid content measurements invalid by comparison to previous measurements

Claims 84, 85, 99, 100 and 101 all require comparing the set of measured impedances indicative of fluid content to prior measured impedances and declaring the data set valid or invalid as a result of this comparison. Neither Combs ’861 nor Scheulke discloses or suggests this aspect of the claimed invention. This aspect of the claimed invention doesn’t even relate to lead integrity determinations as in Scheulke and clearly is not present in Combs. The comparison of impedances in Combs is to detect trends in fluid levels. These comparisons, directly contrary to the claims, are based upon the assumption that the measurements are all correct.

In the first Office Action, the Final Office Action and the Advisory Action, the Examiner does not address this issue. Clearly, the measurement system in Combs

does not provide this capability. The Examiner still does not specifically refer to this issue in the Examiner's Answer.

According to the Examiner's new argument as quoted above, the only relevance of Scheulke is to suggest using the measurement system of Combs as it stands to check lead integrity, which is irrelevant to these claims. The mere suggestion of using the existing impedance measurement system of Combs to measure lead integrity does not provide this function and clearly does not result in this aspect of the invention. If the Examiner's new argument is intended to be the basis for rejection, these claims therefore are respectfully asserted to be allowable as a matter of law over the Examiner's new argument, regardless of the patentability of the remaining claims.

It is therefore respectfully asserted that the rejection of record for these claims is per-se inadequate under the Patent Office guidelines for obviousness rejections.

Withdrawal of the rejections of these claims is respectfully requested.

E. Claims 82 and 98 - Declaring lead integrity measurements invalid by comparison to previous measurements

Claims 82 and 98 all require comparing the set of measured impedances indicative of lead integrity to prior measured impedances and declaring the data set valid or invalid as a result of this comparison. Clearly, the measurement system in Combs does not provide this capability. The Examiner does not even refer to this issue in the Examiner's Answer.

According to the Examiner's new argument as quoted above, the only relevance of Scheulke is to generally suggest using the measurement system of Combs to check lead integrity. If the Examiner's new argument is intended to be the basis for rejection, these claims therefore are respectfully asserted to be allowable as a matter of law over

the Examiner's new argument, regardless of the patentability of the remaining claims. The mere suggestion of the existing impedance measurement system of Combs does not provide this comparison function and clearly does not result in this aspect of the invention. The comparison of impedances in Combs is to detect trends in fluid levels. These comparisons, directly contrary to the claims, are based upon the assumption that the measurements are correct.

The Examiner previously referred briefly to this issue in the Final Office Action in conjunction with the previous argument requiring importing the measurement mechanisms of Scheulke into Combs. This previous argument has been replaced by the inconsistent new argument and thus is withdrawn.

Applicants adequately refuted the previous argument in the Appeal Brief and this is presumably why the new argument has been advanced. The new argument, even if accepted, still doesn't produce a device according to the claims. It is therefore respectfully asserted that the rejection of record for these claims is per-se inadequate under the Patent Office guidelines for obviousness rejections.

Withdrawal of the rejections of these claims is respectfully requested.

Conclusion

It is again respectfully requested that any further new grounds of rejection be made in the form of a non-final rejection, as no appealed claims have been amended in a manner that would allow for a second final rejection based upon new grounds.

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned attorney to attend to these matters.

The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

Date: August 10, 2011

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